

## **REMARKS**

### **A. BACKGROUND**

The present Amendment is in response to the Office Action mailed May 24, 2010. Claims 1, 4-8, 13, 21-31, and 33 were pending and rejected in view of cited art. Claims 1, 4-5, 21-22, and 24-27 are amended. Claims 1, 4-8, 13, 21-31, and 33 remain pending in view of the above amendments, with 1, 21, and 24 being independent.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, are consistent with the Examiner's understanding.

### **B. CLAIM OBJECTION AND REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH**

The Office Action objected to claim 1 because of certain informalities. The Office Action also rejected claim 1 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In response, independent claim 1 has been amended as presented herein. In view of the amendments to claims 1, Applicant respectfully requests withdrawal of the objection and rejection of independent claim 1.

### **C. PRIOR ART REJECTIONS**

The Office Action rejected claims 1, 4-8, 13, 21-27, 30, and 33 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,960,410 (*Pinchuk*) in view of U.S. Publication No. 2002/0072730 (*McGill*) and further in view of U.S. Publication No. 2004/0102719 (*Keith*). Claims 28 and 29 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Pinchuk*, *McGill*, and *Keith* as applied to claim 27, and further in view of U.S. Publication No. 2003/0050600 (*Resseman*).

Applicant respectfully submits that the independent claims as presented for reconsideration are not anticipated nor made obvious by *Pinchuk* either singly or in combination with any other cited reference of record.<sup>1</sup> In particular, *Pinchuk* discloses "[a] catheter having a two-part tubular member that defines a passageway which extends completely through the catheter" (Abstract). The catheter includes an "inner tube 22 [that] includes a first rather stiff plastic tube 60 that extends from the bifurcating adapter 30 to that catheter's distal end 24. At a region 62 slightly proximal of the balloon 12 (FIG. 3), the tube 60 is machined . . . or alternatively necked down" (col. 3, ll. 18-23). "A second more flexible tube or sheath 24 covers and is bonded to the reduced diameter portion of the tube 60 from the start of tube's reduced diameter to the catheter's distal end 24" (col. 3, ll. 45-48). This sheath 24, thus, extends from "the start of tube's reduced diameter to the catheter's distal end 24" Id. *Pinchuck* neither teaches nor suggests that the more flexible sheath extends distally from a distal end of the tube 60 because it "is bonded to the reduced diameter portion of the tube 60 from the start of tube's reduced diameter to the catheter's distal end 24" Id. Even if you consider, *arguendo*, the reduced diameter portion of tube 60 to be more flexible than the remainder of tube 60, a distal end of the reduced diameter more corresponds to the distal end of tube 60; they are the same.

*McGill* discloses "methods and apparatus for protecting the *proximal end* of a medical device" (Title)(emphasis added). Structures are provided at the proximal end of the medical device of McGill that provide kink protection. For instance, kink protection portion 205 is "bonded with adhesive or by other means to the outside of the proximal hypotube 104" functioning as a handle usable to manipulate a pull wire to open or close an embolic protection device (para. [0130]). Alternatively, this kink protection can be applied to "an occlusive device for use in an occlusion balloon system . . . [where] a valve is inserted onto a hollow guidewire to control inflation of a balloon on the guidewire" (para. [0136]). In both cases, the kink protection is provided where at least one structure, such as the pull wire or valve is movable relative to another structure, such as the hypotube or hollow guidewire. Applicant has been unable to identify any portion of *McGill* that describes providing kink protection to structures that are not moveable relative to each other.

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<sup>1</sup> Any amendments to claims other than those which are expressly relied upon in overcoming the rejections on art have been made simply to insure consistency in claim language, to correct typographical or grammatical errors, or to correct other errors of a formal, non-substantive nature, but not to otherwise narrow the claims in scope for any reason.

Furthermore, notwithstanding *McGill* being cited for the proposition that it teaches "a configuration wherein proximal and distal pipes met end to end at a transition, wherein kink protection is provided about the transition at least partially overlapping the proximal and distal pipes (Figs. 16 and 17)", such illustrated embodiments neither teach nor suggest that such a transition occurs within another structure, such as a catheter shaft (Office Action, p. 5). Rather, with the proximal hypotube 104 functioning as a handle, it is not clear how the handle and a portion of the outer shaft member 22 can be disposed within another catheter and still be accessible to operate the filter. Similarly, in the case of the valve, it is unclear how an operator could manipulate the valve with it being within a catheter. There is no teaching or suggestion in *McGill* of using such kink protection within another catheter.

Thus, even if, *arguendo*, *McGill* discloses "proximal and distal pipes [that] meet end to end" there appears to be no teaching or suggestion that such relationship of pipes occurs within a catheter shaft. Furthermore, Applicant respectfully submits that there would be no reason to combine the teaching of *McGill* and *Pinchuk* because the kink protection of *McGill* is associated with preventing kinking of one movable structure within another and the tube 60 and sheath 64 and not moveable relative to each other. Still further, there would be no reason to combine the teachings of *McGill* and *Pinchuk* because, and mentioned in the Office Action Response of 23 March 2009, *Pinchuk* states that the combination of tube 60 and sheath 64 "is advantageous since it allows the catheter to be inserted more easily along a tortious path through a subject's cardiovascular system *without kinking* and with improved pushability" (col. 3, ll. 51-54<sup>2</sup>).

Thus, *Pinchuck* in combination with *McGill* clearly does not anticipate or make obvious applicants' claimed stent (e.g., see claims 1, 21, and 24) which requires, *inter alia*,

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<sup>2</sup> The Office Action mailed 6/12/2009 suggested that "increased resistance to kinking is often desirable in tubular medical articles and therefore the aforementioned increase in resistance to kinking at a particular location known to be susceptible to kinking would be sufficient reason to combine the two methods of kink resistance as presented by Pinchuk and McGill et al" (Office Action p.6). Applicant respectfully disagrees.

In addition to the reasons mentioned in the Remarks, Applicant respectfully disagrees with the proposed combination because adding a secondary layer of kink resistance to a device already including sufficient kink protection to allow the illustrated and described device to "pass through a subject's cardiovascular system without kinking and with improved pushability" appears to be unwarranted and would increase the size of a device that is often inserted through vasculature, and, thus, is subject to size constraints. It is not clear to Applicant why one skilled in the art would increase resistance to kinking at a location that already has sufficient kink protection to allow the medical article to perform its desired function in light of the attendant size constraints. It appears, therefore, the impermissible hindsight is being used with the proposed combination.

- “the guiding wire lumen being formed *within the catheter shaft* and from a proximal reinforcing pipe having a selectable length and a distal plastic pipe extending distally from a reinforcing pipe distal end, the inflation lumen being formed between an exterior surface of the proximal reinforcing pipe and the distal plastic pipe and an interior surface of the catheter shaft” (Claim 1)(emphasis added)
- “the guide wire lumen being formed *within the catheter shaft* and by a proximal reinforcing pipe having a selectable length and a distal plastic pipe extending distally from a reinforcing pipe distal end, the proximal reinforcing pipe comprising a material having a greater rigidity than the distal plastic pipe” (Claim 21, emphasis added)
- “the catheter shaft comprising a guide wire lumen extending from the proximal end to the distal end, the guide wire lumen being formed *within the catheter shaft* from a proximal reinforcing pipe and a distal plastic pipe disposed end to end with the distal end of the proximal reinforcing pipe abutting the proximal end of the distal plastic pipe, the distal plastic pipe extending distally from the distal end of the proximal reinforcing pipe” (Claim 24, emphasis added).

Accordingly, for at least the reasons noted, independent claims 1, 21, and 24 and the claims depending therefrom<sup>3</sup> are neither anticipated nor made obvious by *Pinchuk*, either singly or in combination with any other prior art of record<sup>4</sup>, and thus reconsideration and withdrawal of the rejection is respectfully requested.

#### **D. CONCLUSION**

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will

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<sup>3</sup> Emphasis herein of the differences between the independent claims and the prior art are equally applicable to the dependent claims 4-8, 13, 22, 23, 25-31 and 33, but this does not mean, on the other hand, that these are necessarily the *only* differences between the claimed invention and the prior art of record. Applicants thus do not acquiesce in any asserted rejections of the dependent claims 4-8, 13, 22, 23, 25-31 and 33.

<sup>4</sup> *Keith*, *Ressemann*, and *Davis-Lemessy* were cited as secondary references. *Keith* was cited for the proposition that it discloses using “a polymer tube, such as PTFE (136) as a lubricious inner liner for a guide wire lumen (Paragraph [0061])” (Office Action, p. 5). *Ressemann* was cited for the proposition that it discloses “plasma treating for increasing adherence”, while *Davis-Lemessy* was cited for the proposition that it discloses “use of a nylon tube in the construction of a catheter” (Office Action, pgs. 6 and 7). That said, none of these references otherwise add anything in terms of reading on the claims as amended herein, particularly in reference to those claimed limitations noted above which clearly define over *Pinchuk* and *McGill*. Thus, even assuming *arguendo* that any of the references to *Keith*, *Ressemann*, and *Davis-Lemessy* are properly combinable with *Pinchuk* and/or *McGill*, such combinations are clearly distinguished by the claims for the reasons already noted in reference to *Pinchuk* and/or *McGill*.

be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

For at least the foregoing reasons, Applicant respectfully submits that the pending claims are neither anticipated by nor made obvious by the art of record. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 25<sup>th</sup> day of October, 2010.

Respectfully submitted,

/Paul N. Taylor, Reg.# 57271/

PAUL N. TAYLOR

Registration No. 57,271

Attorney for Applicant

Customer No. 57360

Telephone No. 801.533.9800

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